Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane (Room. 1060),
Rockville, MD 20852.
USA

17th June 2002

RE: Comments on "Draft FDA Guidance for Industry; Electronic Records; Electronic Signatures, Timestamps" Docket No. 00N-1542

Dear Sir/Madam:

GlaxoSmithKline a research-based pharmaceutical company is engaged in the discovery, development, manufacture, and sale of pharmaceutical products. We welcome the opportunity to submit comments on aspects of the Draft Guidance.

Comments:

1) Section 5 Key Principles and Practices. Guidance on calendar clock changes (e.g. changing between winter and summer time) would be useful. It is possible under such clock changes to have duplicate timestamps for actions conducted at different times. We suggest this section should emphasise that timestamps should allow easy, reliable, repeatable and unambiguous determination of the time an action took place (see also comment 5).

2) Section 5.1.1 Synchronization. The terms 'set correctly' and 'set properly' are not defined. We suggest inclusion of a statement of setting clocks to pre-defined accuracy and reference to Section 5.3 Time Zone as a clarification of what is required. Different levels of clock accuracy are acceptable in different business process scenarios depending, for instance, on whether timestamps are used solely to indicate a sequence of events or whether they are used to calculate time intervals between events.

3) Section 5.1.1 Synchronization, with regard to computers not on a network, sets forth procedures expected for periodically verifying the time on each and every computer. Some organisations have many thousands of such computers so guidance on how often a computer system needs to be checked and what is an unacceptable time difference that prompts re-synchronization is very important in relation to the resource impact of this activity. We suggest the guidance make reference as appropriate to the use of a criticality assessment based on business process integrity and clock accuracy to determine the frequency of clock checks.

4) Section 5.2 Systems Clock Security. Some COTS systems such as Windows allow configuration at a personal level so detecting inappropriate changes will have to be done through procedural checks. This could have significant resource implications depending on who can conduct the check, how often checks are required, and how many computers there are to check. We suggest the guidance make reference as appropriate to the use of a criticality assessment based on business process integrity and clock accuracy to determine the frequency of clock checks (see also comment 3).

5) Section 5.3 Time Zones. The inclusion of the 'Time Zone Reference' in the timestamp will mean a modification to current industry standard timestamps and invalidate current timestamps that do not contain this information. We suggest third and forth paragraphs in this section be re-written to emphasise that time zone information within the time stamp or associated audit trail should allow easy, reliable, repeatable, and unambiguous determination of the reference time zone. It should be acceptable to exclude 'Time Zone Reference' information from timestamps for computer systems that do not operate across different time zones so long as the time zone can be deduced. The inclusion of time zone information within a timestamp can then be suggested as an appropriate development for systems operating across different time zones.

6) Section 6 Other Uses of Time Stamps in Electronic Recordkeeping. The inclusion of inappropriate uses and bad practice examples would be useful to assist education programmes. Examples to consider might include: uncoordinated local calendar clock changes that vary across different time zones (see comment 1), inappropriate clock set-up and periodic checks leading to ambiguous timestamps (see comments 2, 3 and 4), and an inability to determine the relevant time zone for timestamps where this information is critical (see comment 5).

We appreciate the opportunity to comment. Thank you for your consideration.

Sincerely,

Dr Guy Wingate
Director, Global Computer Validation